# IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Patrick SCHIFRINE et al.

Conf. 9488

Application No. 10/564,547

Group 3733

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Examiner Fisher, Elana B.

DEVICE FOR ASSISTING IN TOTAL KNEE PROSTHESIS IMPLANTATION

## AMENDMENT

Assistant Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

May 27, 2008

Sir:

In response to the Office Action mailed February 26, 2008, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begin on page 2 of this paper.

Remarks begin on page 9 of this paper.

## AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings of claims in the application:

#### LISTING OF CLAIMS:

- 1. (currently amended) Device A device for positioning a total knee prosthesis, comprising:
  - a tensioning component (1) having[[:]]
- a <u>tensioning component</u> plate (2) which is capable of being configured to be supported on a tibial cutting surface,
- sliding means (3) extending from said tensioning
  component plate (2),
- a slide (5) which is capable of being displaced displaceable on [[a]] the sliding means (3) in a direction substantially perpendicular relative to the tensioning component plate (2) and which has having means (6, 11) for being temporarily fixedly joined to an ancillary component (20), which comprises

the ancillary component (20) i) comprising a centromedullary rod (22) and a tibial plate (21) and a centro-medullary rod (22) extending from the tibial plate (21), and ii) which is capable of receiving configured to receive adjusting means of variable thicknesses, the adjusting means positioned beforehand at the end of the a femur when the a knee is in a state of

flexion at approximately 90°, allowing to allow spacing in an extended state of the an articulation to be obtained,

- for displace displacing the slide (5) and tension thereby tensioning the knee when by way of the tensioning component plate (2) is pressed on the a tibial cut and the ancillary component (20) which is fixedly joined to the slide (5),
- a drilling guide (30) which is capable of being mounted on the sliding means (3) and which has having drilled holes (37) which for allow the subsequent positioning a cutting block on the femur of a cutting block which allows the to allow posterior femoral cuts to be brought about,
- [[-]] the <u>drilling</u> guide (30) being able to comprise or be associated with a <u>configured to receive</u> means for palpating [[the]] <u>an</u> anterior portion of the femur <u>in order to position for positioning</u> the <u>drilling</u> guide (30) in alignment with this the anterior portion, <u>and</u>
- and reference means (EF) which determine for determining the a position of the slide (5) and/or the drilling guide (30) relative to the tensioning component plate (2) of the tensioning component (1) and therefore determine the an interarticular space available in [[a]] the state of flexion,

the device thus allowing either the  $\underline{a}$  position of the  $\underline{a}$  distal femoral cutting plane to be determined by determining the  $\underline{a}$  difference between the  $\underline{a}$  spacing in the  $\underline{a}$  state of extension

and the <u>a</u> space in the state of flexion, or, in the case of a distal cut which is carried out immediately, the <u>a</u> position of the <u>a</u> posterior femoral cutting plane to be determined in order to obtain approximate equality between the spacing in the state of extension and the space in the state of flexion.

- 2. (currently amended) Device The device according to claim 1, characterised in that it comprises further comprising:

  a size estimation component (40) which is capable of being configured to be mounted on the sliding means (3) in order to be able to estimate for estimating, using a reference means, the size of the femur and allow allowing selection of a the correct drill guide component (30) to be selected.
- 3. (currently amended) Device The device according to claim 2, characterised in that wherein the dimension of the tensioning component plate (2) is such that the a femoral end can be received between the tensioning component plate and the size estimation component (40), in the manner of a calliper rule.
- 4. (currently amended) Device The device according to claim 1, characterised in that it comprises further comprising:

  a distal cutting guide support (50) which has having i)

  a member (51) which is capable of sliding configured to slide on the sliding means (3) and from which an arm (54) extends

extending from said member (51) which will extend extends parallel with the axis of the knee in [[a]] the state of flexion, and which has ii) means for receiving and for fixing the distal cutting guide at a precise location, the precise location being able to be determined by the a calculation of the difference between the space in the state of flexion and the spacing in the state of extension and the space in the state of flexion.

- 5. (currently amended) Device The device according to claim 1, characterised in that wherein the tensioning component (1) comprises, extending from the plate (2), sliding means (3), on or in which the slide (5) is capable of sliding, this slide (5) being able configured to be displaced by means of an assembly comprising a screw (8) and a nut (10) in order to allow the surgeon to slide the slide (5) and place the knee in a state of tension.
- 6. (currently amended) Device The device according to claim 5, characterised in that wherein the sliding means (3) have an internal runner in which and the slide (5) is guided[[,]] in the internal runner, and

the sliding means have an outer surface which allows for guiding at least the drilling guide (30) and other components of the device to be guided, the slide having a portion which allows the drilling guide to be moved on this device.

- 7. (currently amended) Device The device according to claim 1, characterised in that wherein the drilling guide (30) is constructed so as configured to receive a palpating arm which is capable of pressing configured to press on the anterior surface of the femoral end in order to limit the insertion of the drilling guide on the a guiding means in order to optimise the a drilling position.
- 8. (currently amended)  $\frac{1}{2}$  Device  $\frac{1}{2}$  The device according to claim 1, characterised in that wherein the slide (5) has
- $\underline{i)}$  reliefs (11) which allow for precise positioning, relative to the slide, of the  $\underline{tibial}$  plate (21) of the ancillary component (20), and
- <u>ii)</u> a rapid fixing means (6) which allows <u>for</u> temporarily fixedly joining the <u>tibial</u> plate (21) to be temporarily fixedly joined relative to the slide (5).
- 9. (currently amended) Device The device according to claim 1, characterised in that the further comprising:

a size estimation component (40) for palpating the an anterior end of the femur, is formed in the size estimation component having one piece with a member (41) which is capable of sliding configured to slide on or in the sliding means (3), this the sliding member (41) having a transverse palpating arm (43)

which is articulated about a shaft (44) parallel with the  $\underline{a}$  sliding axis of the member on the sliding means.

10. (new) A device for positioning a total knee prosthesis, comprising:

an ancillary component (20) with a tibial plate (21) and a centro-medullary rod (22) extending from a surface of the tibial plate (21); and

- a tensioning component (1) having
- a tensioning component plate (2) configured to be supported on a tibial cutting surface,
- a sliding means (3) extending perpendicularly from a surface of the tensioning component plate (2),
- a slide (5) on the sliding means (3) and displaceable with the sliding means (3) in a direction perpendicular to the surface of the tensioning component plate (2), and releasably fixedly joined to the tibial plate of the ancillary component (20),
- a motor means (8, 10) for displacing the slide (5) to tension a knee in a mode wherein the tensioning component plate (2) is pressed on a tibial cut and the centro-medullary rod (22) of the ancillary component (20) is in a femoral medullary canal of a femur,
- a drilling guide (30) mounted on the sliding means (3) and having drilled holes (37) for positioning a cutting block

on the femur to allow execution of posterior femoral cuts, the drilling guide (30) configured to receive means for palpating an anterior portion of the femur for positioning the drilling guide (30) in alignment with the anterior portion,

- and reference means (EF) for determining the position of at least one of the slide (5) and the drilling guide (30) relative to the tensioning component plate (2), and for determining an interarticular space available in a state of flexion.

11. (new) The device according to claim 10, wherein the motor means comprises a screw rotatable relative to the sliding means, the screw co-operating with a threaded portion of the slide for displacing the slide relative to the sliding means.

#### REMARKS

The application has been amended and is believed to be in condition for allowance.

Claims 1-9 have been amended for clarity and in consideration of U.S. practice and preferences; the amendments find support in the specification and the drawing figures and introduce no new matter.

New claims 10-11 are introduced to claim the invention in a different form. The new claims find support in the specification and the drawing figures and introduce no new matter.

The Official Action rejected claims 1, 3, 5, 7, 8, and 9 under 35 USC 112, second paragraph, citing improper antecedents in the claims.

In response, claims 1, 3, 5, 7, 8, and 9 are amended to obviate the Official Action's rejection. Reconsideration and withdrawal of the indefiniteness rejection are respectfully requested.

The Official Action rejected claims 1-9 under 35 USC 102(b) as being anticipated by Ferrante et al. (U.S. Patent 5,364,401; hereinafter FERRANTE).

The rejection is respectfully traversed by at least the reasons that follow.

As to claim 1, the Official Action states that FERRANTE discloses a device for positioning a total knee prosthesis comprising a tensioning component having a slide which has means for being temporarily fixedly joined to an ancillary component which comprises a centro-medullary rod and a tibial plate. The Official Action makes reference to Figure 5 and identifies element 72 as the centro-medullary rod.

In response, it is firstly noted that claim 1 has been amended, a stated above.

It is respectfully submitted that FERRANTE does not teach centro-medullary rod as recited by claim 1.

In contrast, FERRANTE teaches a second arm portion 72 of an L-shaped rod member 64 used to provide "referencing means for referencing the guide track 62 vis-à-vis the distal end of the bone to set a zero point reference at a most distal end of the bone," column 4, lines 62-65. The end portion 74 of the rod 64 is placed on, for example, the high point of the rounded projection at the end of a bone (column 6, lines 62-64). There is no teaching in FERRANTE of rod member 64 as adapted to be introduced into a femoral medullary canal of a bone (see specification of the application, page 1, lines 24-25 as to "centro-medullary"; see also Figures 30 and 40). Nor is there any teaching in FERRANTE of the centro-medullary rod as recited extending from a tibial plate, as recited.

Therefore, it is respectfully submitted that FERRANTE does not disclose the centro-medullary rod as recited by claim 1.

It is further respectfully submitted that FERRANTE does not teach motor means (8, 10) for displacing the slide (5) and thereby tensioning the knee by way of the tensioning component plate (2) pressed on a tibial cut and the ancillary component (20) fixedly joined to the slide (5), as recited by amended claim 1.

In contrast, FERRANTE discloses an L-shaped rod member 64 including a first arm 66 pivotally connected to the base portion 60 of the distal cut component, and connected to an axle 68 which can be fixed from rotation by a ball plunger of a lock screw 70 (column 4 line 62 to column 5 line 1). The lock screw 70 is loosened to allow the end portion 74 of the rod 64 to slide and rotate to find the high point of a condyle of a bone (column 6, lines 59-64), but provides no motive force either to slide or to rotate the rod.

either displacing the slide or tensioning a knee. On the contrary, the screws 42,26,32 and the axle 68 and rod 66 have no means to displace anything. At best, the loosening of some of these components would ease the application of an external force upon one of the components, but there is no disclosure

of any means to apply or transfer such a force and thereby effect a displacement as required by claim 1.

Therefore, it is respectfully submitted that FERRANTE does not teach the motor means as recited in claim 1.

Moreover, FERRANTE fails to teach a device to tension a knee. Without the motor means as recited, FERRANTE discloses nothing with which to displace any component and thereby introduce a force that would tension a knee or any other workpiece. At best, FERRANTE teaches an article for preparing a bone to receive a distal implant (column 1, lines 6-10; column 2, lines 3-20; column 2, line 64-65).

It is therefore respectfully submitted that FERRANTE does not anticipate the invention claimed in claim 1.

Accordingly, it is respectfully submitted that claim 1 and claims depending therefrom are patentable for at least the reasons foregoing. Reconsideration and withdrawal of the rejection are respectfully requested.

It is further respectfully submitted that new claims 10 and 11 are patentable for at least the same reasons set forth above as to claim 1 and claims depending from claim 1.

Allowance of the claims is earnestly solicited.

From the foregoing, it will be apparent that applicants have fully responded to the February 26, 2008 Official Action and that the claims as presented are patentable. In view of this,

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applicants respectfully request reconsideration of the claims, as presented, and their early passage to issue.

In order to expedite the prosecution of this case, it is requested that the Examiner telephone the attorney for applicants at the number set forth below if the Examiner is of the opinion that further discussion of this case would be helpful.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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